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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/850,353	05/02/97	KIM Y	PC9563JTJ

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GREGG C BENSON
PFIZER INC
PATENT DEPARTMENT
EASTERN POINT ROAD
GROTON CT 06340

EXAMINER	
WHITE, E	
ART UNIT	**PAPER NUMBER**
1623	11

DATE MAILED: 06/17/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on May 10, 1999.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-3 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

– SEE OFFICE ACTION ON THE FOLLOWING PAGES –

U.S. GPO: 1996-410-238/4009

1. Claims 1-3 are pending in the instant application.

2. The finality of the last Office action filed December 24, 1998 is withdrawn for the reasons disclosed below. Prosecution on the merits is reopened.

3. The Appeal is being held in abeyance.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of the term "desired target solubility" in claims 1 and 2 cannot be determined which renders the claims indefinite. The term "desired target solubility" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryant et al. (US Patent No. 5,624,940).

Applicant claims a method of locating one or more salts of a compound and methods of determining a useful salt, from within a series of salts of a particular medicinal compound, wherein in each invention the methods involves adding salts of compounds to a cyclodextrin solution.

Bryant et al disclose preparation of an aqueous solution inclusion complex or a salt thereof comprising a benzothiophene of formula I (see column 1, lines 11-33). The salt of the Benzothiophene of formula I in the Bryant et al patent is within the scope of a "salt of a compound" in the instant claims. Bryant et al also disclose preparation of pharmaceutical compositions comprising an aqueous solution inclusion complex in combination with a pharmaceutically acceptable carrier, diluent, or excipient. See FORMULATIONS 1-3 and Example 1 of the Bryant et al patent wherein a cyclodextrin solution is combined with the active compound to formed an effective amount of an aqueous solution inclusion complex. The instant claims differ from Bryant et al patent by obtaining a series of salts. The analysis of a series of salts combined with cyclodextrin to determine the salt with optimal solubility does not appear to be patentable over the Bryant et al patent since the method, per se, of combining a salt with the optimal cyclodextrin to form a soluble compound is the same, whether the combination is carried out with a series of salts or just one salt. Screening a variety of drug salts for solubility is routine and would have been obvious to the person of ordinary skill in the art wanting to optimize the water solubility of a drug. Similarly, the screening of a variety of cyclodextrins and their derivatives in order to find the complex that gives the best water solubility is also routine. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made having the Bryant et al patent before him to employ the process of the prior art using a series of salts and a variety of cyclodextrins or derivatives thereof because the skilled artisan would have expected the prior art process to be carried out on a series of salts and cyclodextrins similarly to a process for one salt and one cyclodextrin compound. The claimed method involving the use of a series of salts to be combined with a variety of cyclodextrins to determine their solubility does not appear to be patentable over the combination of a cyclodextrin with one salt of a compound as disclosed in the Bryant et al patent.

8. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szejtli et al. (US Patent No. 4,228,160).

Applicant claims a method of locating one or more salts of a compound and methods of determining a useful salt, from within a series of salts of a particular medicinal compound, wherein in each invention the methods involves adding salts of compounds to a cyclodextrin solution.

Szejtli et al disclose preparation of an inclusion complex of cyclodextrin and indomethacin and further show that a physical mixture of an ammonium salt of indomethacin and cyclodextrin is well known in the art (See column 2, lines 26-33). The ammonium salt of indomethacin which is disclosed in the Szejtli et al patent is within the scope of the instant claimed "salt of a compound". The instant claimed method differ from the Szejtli et al patent by obtaining a series of salts. The analysis of a series of salts combined with cyclodextrin to determine the salt with optimal solubility does not appear to be patentable over the Szejtli et al patent since the method, per se, of combining a salt with the optimal cyclodextrin to form a soluble compound is the same, whether the combination is carried out with a series of salts or just one salt. Screening a variety of drug salts for solubility is routine and would have been obvious to the person of ordinary skill in the art wanting to optimize the water solubility of a drug. Similarly, the screening of a variety of cyclodextrins and their derivatives in order to find the complex that gives the best water solubility is also routine. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made having the Szejtli et al patent before him to employ the process of the prior art using a series of salts and a variety of cyclodextrins and derivatives thereof because the skilled artisan would have expected the prior art process to be carried out on a series of salts and cyclodextrins similarly to a process for one salt and one cyclodextrin compound. The claimed method involving the use of a series of salts to be combined with a variety of cyclodextrins to determine their solubility does not appear to be patentable over the combination of a cyclodextrin with one salt of a compound as disclosed in the Szejtli et al patent.

9. All the pending claims of record (claims 1-3) are rejected.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. White
White
June 15, 1999

Gary L. Kunz
GARY L. KUNZ
PRIMARY EXAMINER
GROUP 1200